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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,450	11/27/2000	Wolfgang Fleischer	228.1007	9935

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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/701,450	Fleischer
Examiner	**Art Unit**
Gollamudi Kishore	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 6, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, 4-14, 16-18, 22-24, and 26-57* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 4-14, 16-18, 22-24, and 26-57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *'d 10 ar*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The request for the extension of time, amendment filed on 9-6-02 are acknowledged.

Claims included in the prosecution are 1-2, 4-14, 16-18, 22-24 and 26-57.

Claim Rejections - 35 U.S.C. § 112

1. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

2. **Claims 1-2, 4-14, 16-18, 22-24, 26-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liposomes containing povidone iodine, does not reasonably provide enablement for generic 'wound healing agent' and anti-septic agent' combined with a particulate carrier or various particles claimed in claim 2 and as set forth below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.**

Instant claims are drawn to compositions and a method of administration of compositions in treating infections of the LOWER respiratory tract. The claimed diseases include pneumonia, cystic fibrosis , tuberculosis, and even HIV. According to the specification even B vitamins come under the category of wound healing agents. There is no

adequate disclosure of how a B vitamin can accomplish the claimed functions in the treatment of said diseases. Instant specification does not provide adequate support for the broadly claimed 'antiseptic', anti-inflammatory agents and wound healing promoting agents and 'particulate carrier'; for example, claim 26 defines an anti-inflammatory agent as antiseptic, antibiotic, corticosteroid and wound healing promoting agent; the specification also does not adequately describe what 'functional tissue remodeling' is and how the method is practiced as claimed in the method claims. Instant specification also does not teach how one can apply topically to the respiratory tract and treat or prevent diseases such as HIV and opportunistic diseases. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to liposomally encapsulated povidone iodine and treatment of specific diseases.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that 'anti-septic agents' and 'wound healing agents' are known in the art. This might be so; however, applicant has provided neither data nor rationale for the ability of the agents such as B vitamins and Povidone Iodine in treating diseases such as tuberculosis, cystic fibrosis and HIV. With regard to the issue of 'functional and cosmetic tissue remodeling' applicant directs the examiner's attention to pages 5 and 6. It is unclear as to how the cited paragraph is applicable when the tissue involved is 'lower respiratory tract' as claimed in instant claims. The rejection is maintained.

3. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 4, 5, 6, 8, 10, 14, 16, 24, 26, 37, 46-47 and 56-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between 'organic disinfectants' and rest of the components such as alcohols, phenols, etc., recited in claims 4 and 27 is unclear. The latter compounds are organic.

The term, 'large' in claims 2 and 24 is a relative term and thus, indefinite. Applicant's arguments have been fully considered, but are not found to be persuasive. Instant specification does not provide a specific definition for this term.

According to claim 1 the composition contains only one anti-septic agent and one wound healing agent; however, claim 8 recites, 'at least one'. This is improper.

What are 'conserving agents' and 'consistency-forming agents' as recited in claim 14?. Applicant's arguments that one skilled in the art would understand the terms are not persuasive since no evidence is provided.

What is being conveyed through claims 16 and 37? What are 'compacted solid medicament reservoir' and 'ring-tablet'? What is the difference between a suspension and a dispersion? According to claim preamble, the carrier is a particulate carrier; then how can that be in a solution form? This claim requires a thorough restructuring. This rejection is maintained since applicant has not adequately addressed the issue.

What is being conveyed through claim 26? The claim recites anti-inflammatory agents and then recites the same combination of active agents recited in the parent claim.

Claim 56 is not further limiting claim 55 in terms of sizes. The range in claim 55 is 10 - 20 microns whereas the range in claim is 1-6 microns. Similar is the case with claim 46 which is dependent from claim 10.

The examiner once again suggests a thorough restructuring of the claims and submit a clear copy of the claims.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 22-24, and 26-43, and 51-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26, 29-47 and 51-53 of copending Application No. 09/701220. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims recite 'a method of preventing or treating lower respiratory tract by external application' whereas the method claims in the copending application are drawn to 'a method applicable to the throat and the specification in the copending application appear to define throat as including lower respiratory tract.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-2, 4-14, 16-18, and 40-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,863,556. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic language encompasses the specific components recited in the claims of said patent.

This rejection is maintained in the absence of neither arguments nor a terminal disclaimer.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless --**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

10. Claims 1-2, 9-12, 14-16, 19-26, 32, 34-39, 42, 43, 44, 46, 47, 51, 53, 54, 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Knight (5,049,388).

Knight discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-5 microns. The drugs include antibiotics, antiviral agents and steroids (note the abstract, Tables I and II, examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Knight does not teach or suggest antiseptic agents which promote healing of wounds. The examiner disagrees. Knight clearly teaches the delivery of antibiotics and antiviral agents (anti-septic or wound healing agents) for the treatment of diseases of respiratory tract. The relevant sections have already been indicated.

11. Claims 1-2, 9-12, 14-16, 19-26, 32, 34-39, 42, 43, 44, 46, 47, 51, 53, 54, 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Radhakrishnan (5,049,389).

Radhakrishnan discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-5 microns. The drugs include antibiotics, antiviral agents and steroids (note the abstract, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Radhakrishnan does not teach or suggest antiseptic agents which promote healing of wounds. The examiner disagrees. Radhakrishnan clearly teaches the delivery of antibiotics and antiviral agents (anti-septic or wound healing agents) for the treatment of diseases of respiratory tract.

12. Claims 1-2, 9-12, 14-16, 19-26, 32, 34-39, 42, 43, 44, 46, 47, 51, 53, 54, 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Prince (5,290,540).

Prince discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-10 microns. The drug combination includes antibiotics, antiviral agents and steroids (note the abstract, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Prince does not teach or suggest antiseptic agents which promote healing of wounds. The examiner disagrees. Prince clearly teaches the delivery of antibiotics and antiviral agents (anti-septic or wound healing agents) for the treatment of diseases of respiratory tract.

13. Claims 1-2, 4-14, 16-18 and 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 7-145081 or EP 0939373 of record.

JP and EP disclose the same composition (note the abstract and the English translation of JP and entire article of EP). The intended use has no patentable significance in the composition claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the references teach preparations useful in the treatment of external wounds. This argument is not found to be persuasive since as already pointed out above, the intended use has no significance in composition claims.

14. Claims 1-2, 4, 9, 11-12, ,14-16, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreier (Journal of Controlled release, 1993) of record.

Schreier discloses liposomal compositions containing antimicrobials such as pentamidine, glutathione and superoxide dismutase (note the abstract, Tables and figures).

Claim Rejections - 35 U.S.C. § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

16. Claims 1-2, 4-14, 16-18, 22-24, and 26-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight or Radhakrishnan or Prince or Schreier cited above.

Knight, Radhakrishnan, Prince and Schreier do not teach the administration of all of the claimed compounds and the treatment of wounds caused by different infections. However, since the purpose of Knight, Radhakrishnan and Prince is to administer compounds to the respiratory tract to treat disease conditions in liposomal form, it would have been obvious to one of ordinary skill in the art to use any antiseptic agent or wound

healing agent, with a reasonable expectation of success. They also do not teach the administration of the composition for the infections which occur during remodeling or repairing the lower respiratory tract. However, it is deemed obvious to one of ordinary skill in the art that the wound healing compositions can be applied during any state wherein the wounds are susceptible to infectious agents, with the expectation of similar anti-septic effect.

15. Claims 4-6, 17-18, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP or EP in combination with knight or Radhakrishnan or Prince or Schreier cited above or vice versa.

The teachings of JP, EP, Knight, Radhakrishnan, Prince and Schreier have been discussed above. What is lacking in JP or EP is the teaching of the use of the composition for the treatment of diseases caused by the microbes in the respiratory tract. In the absence of showing unexpected results, it is deemed obvious for one of ordinary skill in the art to use an anti-septic agent and a wound healing promoting agent taught by JP or EP to any part of the body including the respiratory tract, which has a microbial infection and a wound with the expectation of reasonable success since the references of Knight, Radhakrishnan and Prince show the common knowledge in the art of using a combination even for the respiratory tract. One of ordinary skill in the art would have been motivated to use PVP-iodine taught by JP, and EP as a drug in the liposomal compositions of Knight,

Radhakrishnan or Prince or Schreier with the expectation of obtaining similar results since PVP-Iodine is a known anti-septic agent as shown by JP and EP.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a

properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 21, 2002